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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,752	11/21/2001	Darja Fercej Temeljotov	104101.B700017	5309

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
12/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/913,752	FERCEJ TEMELJOTOV ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/28/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71,72,76-82 and 84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71,72,76-82 and 84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of t/e previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/28/2009 has been entered.

Status of Application

2. The Examiner acknowledges receipt of the amendments filed on 09/28/2009 wherein claims71, 80, 82 and 84 have been amended and 83 has been cancelled.

3. Claims 71, 72, 76-82 and 84 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

4. Applicants arguments filed 09/28/2009 regarding the objection of claim 71 made by the Examiner has been fully considered and is found persuasive. This has been overcome by amendment to the claims.

5. Applicants arguments filed 09/28/2009 regarding the rejection of claims 71-72 and 76-84 made by the Examiner under 35 USC 112 second paragraph have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims.

6. Applicants arguments filed 09/28/2009 regarding the rejection of claims 71-72 and 76-84 made by the Examiner under 35 USC 103(a) over Akiyama et al. (WO 98/42311) in view of Farah et al. (WO 98/14176) have been fully considered and they are found persuasive. This rejection has been overcome by amendment

7. Applicants arguments filed 09/28/2009 regarding the rejection of claims 71-72 and 76-78 and 80-83 made by the Examiner under 35 USC 103(a) over Briskin et al. (WO 95/22319) in view of Gibson et al. (US 5811120) and Evenstad et al. (US 5126145), evidenced by Methocel and WO 98/42311 have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims.

8. Applicants arguments filed 09/28/2009 regarding the rejection of claim 79 made by the Examiner under 35 USC 103(a) over Briskin et al. (WO 95/22319) in view of Gibson et al. (US 5811120) and Evenstad et al. (US 5126145), evidenced by Methocel and WO 98/42311 in further view of Khan et al. (US 5656296) have been fully considered and they are found persuasive. This rejection has been overcome by amendment to the claims.

New Rejections, Necessitated by Amendment

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. **Claims 71, 72, 76-82 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akiyama et al. (WO 98/42311; of record) in view of Al-Razzak et al. (US 6010718; field 04/11/1997).**

12. Akiyama teaches a gastrointestinal mucosa adherent matrix adapted to stay long in the gastrointestinal tract for sustained drug release. The gastrointestinal mucosa-adherent matrix which is solid at ambient temperature includes a matrix in which each matrix particle containing a polyglycerol fatty acid ester and/or a lipid and an active ingredient has a coating layer comprising or containing the viscogenic agent.

13. Examples of viscogenic agent include polymers containing carboxyl groups or salts thereof, cellulose ethers, polyethylene glycols having molecular weights not less than 200,000, and naturally-occurring mucous substances. The preferable viscogenic agents are those having a viscosity in the range of 3 to 50,000 cps, preferably 10 to 30,000 cps, and more preferably 15 to 30,000 cps as a 2 percent by weight aqueous solution thereof at 20.degree. C. Cellulose ethers taught include hydroxymethylcellulose and hydroxypropylmethylcellulose (HPMC) (see page 17, lines 10-35 and page 18, line 36). The viscogneic agent is taught in a preferable amount of 1-20% (see page 19, lines 10-15).

14. The matrix may also comprise a polyglycerol fatty acid ester. The polyglycerol fatty acid esters includes behenyl glycerides and the lipids include glycerol fatty acid esters wherein behenic acid is taught as a fatty acid (see page 8, lines 1-5, page 10, and page 12, lines 8-36). The lipid is utilized in an amount of 5-98%.

15. The active includes antimicrobial substance and preferably clarithromycin. See page 14, lines 25-30 and page 15, lines 1-2. The active is used in an amount of 0.005-95% and preferably about 10 to about 50% (see page 26, lines 12-20).

16. The solid composition may be coated with a coating material including hydroxypropylmethylcellulose phthalate (see page 22, lines 15-25 and page 23, lines 30-35). The solid dosage form includes tablets (see page 25, line 14). The composition includes surfactants (see page 29, lines 1-15).

17. Akiyama does not teach the clarithromycin being present in the tablet in an amount of 500 mgs nor does Akiyama teach including HPMc in an amount of 150 mgs.

18. Al-Razzark is directed to extended release formulation of erythromycin derivatives. Example 1 teaches using clarithromycin in an amount of 500 mgs and low-viscosity HPMC in amounts of 100, 200 and 300 mgs. It's indicated that this amount of clarithromycin is useful for the treatment of microbial infections (see column 3, lines 40-45).

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Akiyama and Al-Razzak to arrive at a composition comprising glycerol behenate and 500 mgs of clarithromycin. As Akiyama teaches that clarithromycin may be delivered by the tablet, any ordinary person would have looked to the art for suitable amounts of clarithromycin for delivering to a subject. If such an undertaking resulted in the identification of 500 mgs, as Al-Razzak teaches, then such would have been the result of ordinary skill and common sense. Including such an amount of clarithromycin would have been obvious as Al-Razzak suggests that 500 mgs is suitable for the prophylaxis to microbial infections. With respect to the amount of HPMC (weight percent and mg amount), this

is obvious as Akiyama incorporates viscogenic agent is incorporated preferably amount of the viscogenic agent is 1-20%, which encompasses Applicants "about 13-18 weight percent". Moreover, Al-Razzak teaches tablets comprising 100, 200 and 300 mgs of HPMC which provide sustained release benefit. It would have been readily apparent to any ordinary person to pick and choose from values within these ranges, i.e. 150 mgs with a reasonable expectation that that value too would provide a sustained release benefit. With respect to the inclusion of glyceryl behenate, this is also obvious as it is suggested by Akiyama to be used in an amount of 5-98% of the tablet weight. One would have been motivated to include glyceryl behenate as it's known to provide sustained release properties. With respect to the concentration (weight percent and mg amount) of glyceryl behenate, it would have been well within the skill of an artisan to manipulate the concentration and mg amount based on the general disclosure provided by the prior art absent evidence of the unexpectedness of the claimed range. It's noted that the taught range by Akiyama encompasses the instantly claimed range, as such, the mg amount would necessarily stem from knowing/having a final target tablet weight. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611
December 10, 2009

/David J Blanchard/
Primary Examiner, Art Unit 1643